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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,115	05/31/2006	Joseph Chaiken	LTM.19-US-WO	2248
59612	7590	04/02/2009	EXAMINER	
KAREN S. CANADY CANADY & LORTZ LLP COMMERCE PLAZA 11340 WEST OLYMPIC BLVD., SUITE 275 LOS ANGELES, CA 90064			WOOD, AMANDA P	
			ART UNIT	PAPER NUMBER
			1657	
			NOTIFICATION DATE	DELIVERY MODE
			04/02/2009	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/596,115	<b>Applicant(s)</b> CHAIKEN ET AL.	
	<b>Examiner</b> AMANDA P. WOOD	<b>Art Unit</b> 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/07</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group I (claims 1-15) in the reply filed on 04 August 2008 is acknowledged. The traversal is on the ground(s) that the two groups relate to a single inventive concept and that a search into the prior art is so related that separate significant search efforts are unnecessary. Based upon Applicant's arguments with respect to the restriction of Groups I and II, the restriction between these groups and the election of species requirement have been withdrawn.

Claims 1-18 are presented for consideration on the merits.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 25 January 2007 has been considered by the examiner, and an initialed and signed/dated copy is included with this Office Action.

### ***Drawings***

The drawings submitted by Applicant on 31 May 2006 have been accepted by the Examiner.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method comprising introducing living cells into a container loaded with D<sub>2</sub>O and characterizing membrane function, and therefore, cell viability, with respect to replacement of H<sub>2</sub>O with D<sub>2</sub>O using the measurement of Raman spectra, does not reasonably provide enablement for a method wherein cell viability is determined by introducing living cells into a container loaded with any deuterated materials and obtaining a vibrational spectra emitted by the living cells wherein the spectra are indicative of metabolism, providing an indication of cell viability. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir.1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the breadth of the

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claims, (2) the nature of the invention, (3) the state of the prior art, (4) the predictability or unpredictability of the art, (5) the relative skill of those in the art, (6) the amount or direction or guidance presented, (7) the presence or absence of working examples, and (8) the quantity of experimentation necessary.

N.B. MPEP 2164.04 states, “[w]hile the analysis and conclusion of a lack of enablement are based on the factors discussed in MPEP § 2164.01(a) and the evidence as a whole, it is not necessary to discuss each factor in the written enablement rejection” and that “[t]he language should focus on those factors, reasons, and evidence that lead the examiner to conclude that the specification fails to teach how to make and use the claimed invention without undue experimentation, or that the scope of any enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims.” Accordingly, the Factors most relevant to the instant rejection are addressed in detail below.

1-2 .Breadth of the claims and the nature of the invention..

In regards to the method of the invention and the breadth of the claims the broadest interpretation that applies is a method of introducing living cells into a container loaded with any deuterated materials and obtaining vibrational spectra emitted by the living cells and then inferring cell viability based upon metabolic activity of the cells indicated by the vibrational spectra.

3-4. The state of prior art and the level of predictability in the art.

The prior art (see, for example, Holman et al 2000) teaches that infrared spectroscopy can be used to study individual living cells and investigate changes in IR spectral features at different points in their cell cycle, including those features which indicate that cells are undergoing various steps in the process of cell death (see, for example, Abstract). In addition, Chaiken et al (US 6,503,478, as cited in the IDS filed on 25 January 2007) teach that deuterated imaging agents, such as water and lipids, can be used in a method of imaging tissue using Raman spectroscopy, obtaining information regarding the distribution of specific endogenous chemical species (see, for example, Abstract and col. 2-3). Furthermore, Holtom et al (2001) provides teachings that an active Raman method, called Coherent Anti-Stokes Raman Scattering (CARS), can be used to selectively image deuterated compounds, such as lipids, thus allowing the visualization of molecules. In particular, Holtom et al teach that to enhance the contrast of these images, deuterated fatty acids are used as an active Raman label, since deuterium is nearly identical to hydrogen but is spectroscopically distinguishable because the vibrational frequency depends upon atomic mass, and that C-H frequencies are therefore shifted by deuterium from about  $3000\text{cm}^{-1}$  to about  $2150\text{cm}^{-1}$  (see, for example, Abstract and page 787, column 1).

The prior art does not specifically teach that any nonspecific deuterated materials may be used to obtain vibrational spectra which would be indicative of cell metabolism, and therefore, cell viability.

5. The relative skill in the art.

The relative skill in the art as it relates to the method of the invention is characterized by that of a M.D. or Ph. D. level individual.

6-7. The amount of guidance present and the existence of working examples.

Applicant provides sufficient guidance in the working examples for one of skill in the art to practice a method of characterizing membrane function of living cells using D<sub>2</sub>O as a replacement for H<sub>2</sub>O. However, Applicant provides no particular guidance in the instant specification regarding a method of providing deuterated materials other than D<sub>2</sub>O and does not provide any working examples or guidance with regard to practicing a method of obtaining a vibrational spectra emitted by living cells and associating such spectra with metabolism so as to provide an indication of viability of the cells, wherein greater metabolic activity is indicative of cell viability.

8. The quantity of experimentation necessary.

The amount of experimentation that is required is undue: while a method of characterizing vibrational spectra of cells using D<sub>2</sub>O or deuterated lipids and obtaining Raman spectra is routine, a method of introducing any deuterated material to living cells to obtain vibrational spectra for the purpose of determining cell viability via cell metabolism is not routine and requires more experimentation. Therefore, in view of the overly broad scope of the claims, the lack of guidance and working examples provided in the specification, and the high degree of unpredictability as evidenced by the prior art, undue experimentation would be necessary for a skilled artisan to make and use the entire scope of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 and 6-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In particular, Applicant recites the phrase “deuterated materials” in claim 1, lines 2 and 4. It is unclear what Applicant means by “deuterated materials” and therefore, this phrase will be given the broadest reasonable interpretation (i.e., any deuterated agent which would reasonably be used by one of skill in the art in obtaining vibrational spectra).

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.



Claims 1-3 and 6-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Chaiken et al (US 6,503,478), as cited in the IDS filed on 25 January 2007.

A method is claimed for determining viability of living cells comprising introducing living cells into a container loaded with deuterated materials and obtaining vibrational spectra emitted by the living cells.

Chaiken et al teach that Raman specific agents, such as water and phospholipids, are used in a method of imaging tissue comprising administering a deuterated imaging agent (i.e., a deuterated material) and performing spectroscopy, particularly Raman spectroscopy (i.e., obtaining vibrational spectra) using a near infrared laser, so as to obtain information regarding the distribution of specific endogenous chemical species by imaging the exogenously applied deuterated agents. Chaiken et al teach that substituting a deuterium for a hydrogen results in a lowering of the vibrational frequency by about 1.414, causing a shift of about 800 to 900  $\text{cm}^{-1}$  for C-H bonds, and about 900 to 1000  $\text{cm}^{-1}$  for O-H bonds (see, for example, Abstract, col. 2, lines 1-20 and 50-67, and col. 3-4).

Therefore the reference is deemed to anticipate the instant claims above.

### ***Conclusion***

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMANDA P. WOOD whose telephone number is (571)272-8141. The examiner can normally be reached on M-F 8:30AM -5PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

APW  
Examiner  
Art Unit 1657

/Ralph Gitomer/  
Primary Examiner, Art Unit 1657